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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/620,691	07/20/2000	David A. Tirrell	30431.5US01	3160
28213	7590	04/20/2004	EXAMINER	
GRAY CARY WARE & FREIDENRICH LLP 4365 EXECUTIVE DRIVE SUITE 1100 SAN DIEGO, CA 92121-2133			GUPTA, ANISH	
			ART UNIT	PAPER NUMBER
			1654	

DATE MAILED: 04/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No. 09/620,691	Applicant(s) TIRRELL ET AL.	
	Examiner Anish Gupta	Art Unit 1654	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 29 March 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
- ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
 - (b) ☐ they raise the issue of new matter (see Note below);
 - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: 1,3,4 and 15-24.

Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____

Continuation of 2. NOTE: the claims have been limited to leucine zipper which would require a new search and or consideration.

Continuation of 5. does NOT place the application in condition for allowance because: of the following reasons:

The arguments have been based upon the entry of the amendment, since the amendment has not been entered, the response is not sufficient to overcome the rejection. However, to expedite prosecution some issues with regards to 112 First paragraph have been addressed.

Applicants state the specification, in combination of knowledge about GCN4 peptide, provide ample written description for the claimed invention. Applicants argue, "The results disclosed for the A1 polypeptide provides confirmatory evidence that, as disclosed for GCN4, substitution of a hydrophobic amino acid with a non-natural amino acid in a heptad leucine zipper domain of a polypeptide can increase the thermal stability of the polypeptide."

Applicants are reminded that the rejection is not based on 112 Enablement, rather it is based on 112 Written description. The crux of the issue, therefore, is that have Applicants provided ample written description to support that the Applicants invented the claimed invention. The claims are product claims, drawn to peptides that contain a non-naturally occurring amino acid within the Leucine Zipper. It is conventionally known that a "leucine zipper" is a peptide (often about 20-40 amino acid residues long) having several repeating amino acids, in which every seventh amino acid is a leucine residue. Such leucine zipper sequences form amphipathic .alpha.-helices, with the leucine residues lined up on the hydrophobic side for dimer formation. Leucine zippers may have the general structural formula known as the heptad repeat (Leucine -X.sub.1 -X.sub.2 -X.sub.3 -X.sub.4 -X.sub.5 -X.sub.6 ;SEQ ID NO:4).sub.n, where X may be any of the conventional 20 amino acids, but is most likely to be amino acids with tight .alpha.-helix forming potential, for example, alanine, valine, aspartic acid, glutamic acid and lysine, and n may be three or greater, although typically n is 4 or 5. Thus, it is unquestionable, the claim qualifies as a genus claim. The MPEP states that the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. Applicants have not fulfilled the written description requirement, since the specification lacks sufficient number of examples to qualify as a "representative number" of examples. The only structural insight given is that the peptide contain a single non naturally occurring amino acid, contain a leucine, and contain amino acids with tight .alpha.-helix forming potential, for example, alanine, valine, aspartic acid, glutamic acid and lysine. The presence of these amino acids, does not give sufficient insight as to structure for the genus claim.

For these reasons and the reasons of record, the rejection is maintained.

[Handwritten signature] 4/12/04

[Handwritten signature: Brenda Brumback]
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